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A Shape Memory Polymer Dialysis Needle Adapter for the Reduction of Hemodynamic Stress within Arteriovenous Grafts

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Abstract—A deployable, shape memory polymer adapter is investigated for reducing the hemodynamic stress caused by a dialysis needle flow within an arteriovenous graft. Computational fluid dynamics simulations of dialysis sessions with and without the adapter demonstrate that the adapter provides a significant decrease in the wall shear stress. *In vitro* flow visualization measurements are made within a graft model following delivery and actuation of a prototype shape memory polymer adapter.

Index Terms—dialysis needle, shape memory polymer, wall shear stress, computational fluid dynamics

1.0 Introduction

Vascular access complications resulting from arteriovenous (AV) graft failures account for over $1 billion per year in the health care costs of dialysis patients in the U.S.[1] The primary mode of failure of arteriovenous fistulas (AVF's) and polytetrafluoroethylene (PTFE) grafts is the development of intimal hyperplasia (IH) and the subsequent formation of stenotic lesions, resulting in a graft flow decline. The hemodynamic stresses arising within AVF's and PTFE grafts play an important role in the pathogenesis of IH. Studies have shown that vascular damage can occur in regions where there is flow separation, oscillation, or extreme values of wall shear stress (WSS).[2] Nevaril *et al.*[3] show that exposure of red blood cells to WSS's on the order of 1500 dynes/cm^2 can result in hemolysis.

Hemodynamic stress from dialysis needle flow has recently been investigated for the role it plays in graft failure. Using laser Doppler velocimetry measurements, Unnikrishnan *et al.*[4] show that turbulence intensities are 5-6 times greater in the AV flow when the needle flow is present and that increased levels of turbulence exist for approximately 7-8cm downstream of the needle. Since the AVF or PTFE graft is exposed to these high levels of hemodynamic stress several hours each week during dialysis sessions, it is quite possible that needle flow is an important contributor to vascular access occlusion.[4]

We present a method for reducing the hemodynamic stress in an AV graft by tailoring the fluid dynamics of the dialysis needle flow using a deployable shape memory polymer (SMP) dialysis needle adapter. Such an adapter is deployed through the needle into the graft where it is actuated into an expanded shape using thermal energy. The expanded adapter has a tube-like shape, in which the distal end has a larger cross-sectional area than that of the needle. When the dialysis session is completed, the adapter is retracted through the needle. In this initial study, we conduct computational fluid dynamics (CFD) simulations to assess the changes in the hemodynamic stress on a graft wall when the SMP adapter is utilized. Additionally, we fabricate a prototype SMP adapter and deploy it in an *in vitro* model of an AV graft.

2.0 Computational and Experimental Setup

A simplified computational setup is used for the CFD simulations (Fig. 1a). The graft is taken to be a straight, non-compliant, circular tube with an internal diameter of 6mm, which is representative of typical PTFE grafts. A 15-gauge dialysis needle is positioned at an angle within the graft to account for percutaneous needle entry. The inlet boundary condition to the graft is a parabolic velocity profile with a flowrate of 1000mL/min. A parabolic velocity profile is also applied to the inlet of the dialysis needle to provide a flowrate of 400mL/min. A zero gradient boundary condition is applied to the outlet of the AV graft, such that all computed variables on the outlet nodes are extrapolated from interior nodes. The blood is assumed to behave like a Newtonian fluid with a constant viscosity of 0.0035kg/m·s and density of 1060 kg/m^3. The fully deployed SMP adapter is represented by a thin tube that extends from the end of the dialysis needle. The adapter has a proximal diameter of 1.6mm, a distal diameter of 2.45mm, and a length of 12.8mm from the needle tip. Unstructured meshes with 4.5e6 and 3.2e6 cells are used to fill computational domain with and without the adapter, respectively, and a time step of 1e-4s is chosen for these unsteady simulations. Using a finite-volume CFD code [5], we solve the unsteady, Navier-Stokes equations for dialysis sessions with and without the adapter.

SMP has the unique ability to recover a pre-programmed shape via a thermal actuation mechanism.[6] When sufficiently below its characteristic glass transition temperature (Tg), the glassy (elastic modulus ~ 10e9 Pa) SMP can maintain a secondary shape that is different than its original pre-programmed shape. As the temperature increases to and beyond Tg, the modulus falls and the rubbery (elastic modulus ~ 10e6 to 10e7 Pa) SMP transforms back to its pre-programmed shape. The transition from the secondary to the primary shape is not sharp; the modulus falls gradually over a span of 10-20°C with the nominal Tg approximately centered in the decline. Upon cooling, the original modulus is nearly completely recovered and the pre-programmed shape is stabilized.

Fabrication of the prototype SMP adapter begins by dip-coating a solution of MM-5520 SMP (DiAPLEX Company Ltd., a subsidiary of Mitsubishi Heavy Industries Ltd.) about an aluminum mandrel, which defines the inner surface of the adapter shape. Depending on the coating number, the SMP is dried at 50^{o}C under nitrogen for 15 to 60min. The mandrel and SMP coating are then vacuum dried for 24 hours at 50^{o}C. To release the adapter from the mandrel, the entire assembly is immersed in acetone, which plasticizes and swells the soft phase of the SMP. The adapter is then vacuum dried at 50^{o}C and 1 Torr for 24 hours. The resulting glass transition temperature, Tg, and wall thickness of the SMP adapter are 75°C and approximately 150-250 microns, respectively. Using UV-cured epoxy (EPO-TEK OG603, Epoxy Technology, Inc.), the SMP adapter is bonded to a 3F catheter (Fastracker – 18MX, Target Therapeutics, Inc.), which is attached to a syringe pump (Harvard Apparatus, model PHD 2000) that simulates the blood flow from a dialysis machine. The SMP adapter is compressed using a balloon wrapping/stent crimping machine (Interface Associates) from an initial maximum diameter of 2.7mm (Fig. 1b) to 1.5mm (Fig. 1c), allowing the adapter to fit through the dialysis needle (Medisystems). To visualize the flow delivered through the dialysis needle, the syringe is filled with room temperature (~21°C) red food coloring and water. The dialysis needle is inserted into a 6mm internal diameter tube (VWR Signature clear PVC tubing) that is used to represent a PTFE graft. Water flow through the model AV graft is supplied with a peristaltic pump (Watson-Marlow, Ltd., Model 505Du). In this initial study, a simple approach is used to deliver thermal energy to the adapter; heated water (78^{o}C) is flushed through the AV graft model to raise the temperature above Tg. Due to limitations in both the peristaltic and syringe pumps, physiological flowrates are not attainable for this initial study. However, the needle and graft flowrates are set to 53 and 100mL/min, respectively, which approximately maintains the physiological flowrate ratio of 400mL/min to 1000mL/min (needle flowrate to graft flowrate) used in the CFD simulations.

3.0 Results

The simulation results for the dialysis session without the adapter demonstrate that the basic flow features are a high-speed jet (mean x-velocity of 2.7m/s) issuing from the needle and a slower background vascular access flow (mean x-velocity of 0.6m/s) within the graft (Fig. 2a). Downstream of the needle tip, the flow quickly becomes unsteady and highly three-dimensional due to a jet shear layer instability that develops on the upstream side of the exiting needle flow. As the jet shear layer instability becomes non-linear, a train of periodic vortices forms across the jet as highlighted by the iso-Q surfaces in Fig. 2b, where Q is the second invariant of the velocity gradient tensor.[7] The needle flow impinges upon the bottom of the graft wall and begins to sweep upwards along the sides to the top of the graft, forming two large-scale helical structures that persist down the length of the graft. Immersed within these helical structures are a host of small-scale, complex, three-dimensional vortices that orbit about and entwine one another, resulting in substantial flow unsteadiness downstream of the dialysis needle. The graft wall experiences increased hemodynamic stresses as a result of the impinging needle jet. This is evidenced by a sharp rise in the WSS (Fig. 3a-b) field in the vicinity of the jet impingement region. Upstream of this region, the WSS is approximately 30 dynes/cm^2, but downstream of it, the WSS rapidly undergoes an eighty-fold increase to nearly 2400 dynes/cm^2. When the fully deployed SMP adapter is present, the needle jet is oriented in the downstream direction and no longer impinges as severely upon the graft wall (Fig. 3a-b). As a result, the WSS (Fig. 3a-b) is substantially reduced. In addition, the larger cross-sectional exit area of the adapter decelerates the needle flow. A comparison of the mean x-velocity of the needle flow at the distal tip of the adapter (1.3m/s) with the mean x-velocity of the background vascular access flow (0.7m/s) at the same x-location shows them to be closer to one another, which could potentially reduce the strength of the shear layer instability that develops downstream of the adapter.

Images of the *in vitro* flow visualization prior to delivery of the SMP adapter are shown in Fig. 4a-b. Although the vascular access and needle flowrates are well below the physiological values used in the CFD simulations, a qualitatively similar flowfield is present in which the needle jet impinges upon the tube wall and wraps upward along the side of the wall. After the compressed SMP adapter is delivered through the dialysis needle, the heated flow within the model graft actuates the adapter to its fully expanded shape (Fig. 4c). Complete actuation occurs within approximately 30 seconds. Following the actuation, room temperature water (~21°C) is pumped through the graft model. The resulting flow visualization image (Fig. 4d) with the deployed adapter demonstrates that the adapter directs the needle jet so that it is slightly more aligned with the background vascular access flow.

4.0 Discussion and Conclusions

Through this initial investigation, we have presented the results of a novel SMP dialysis needle adapter. The CFD simulations demonstrate that the adapter significantly reduces the graft WSS, which could potentially reduce hemolysis and subsequent vascular access occlusion. The successful *in vitro* test indicates that the concept of delivering and actuating a SMP adapter through a dialysis needle has merit and should be further investigated and improved. It is evident that the prototype adapter does not entirely direct the flow in the downstream direction, but rather orients it in a direction that is only slightly inclined with respect to the needle. This can be remedied by casting a longer SMP adapter about a mandrel that has an inherently curved shape. Given the ease of machining and molding the SMP material, this and other modifications can readily be incorporated into alternate adapter designs.

One aspect of the SMP adapter that is simplified in this initial study is the means by which thermal energy is delivered to the SMP material. Since flushing heated water through an AV graft is not an option for in vivo deployment of the adapter, another thermal actuation method is necessary. One method of actuating the current prototype adapter is by delivering optical energy through a diffusing fiber element inserted down the center of the adapter. Our previous work on these optical elements has shown that it is possible to deliver up to 8W of power over arbitrary diffusing profiles, which will allow for the deployment of non-uniform adapter shapes such as that considered in this study.[6] Using a SMP with a lower Tg will reduce the amount of thermal energy needed to achieve actuation and, hence, reduce the risk of thermal damage. If the Tg is lowered to near body temperature (~37°C), the need for external energy delivery is eliminated. In this case, when the adapter is deployed through the dialysis needle and warmed by the vascular access blood flow, it will expand to its primary shape. Because the modulus of elasticity of the SMP remains relatively low when the SMP temperature is near Tg, the adapter can easily be retracted through the needle when the dialysis session is completed. In future work, we plan to explore these and other deployment techniques and determine the effects that the adapter has upon IH formation within *in vivo* AV grafts using animal models.

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Fig. 1. (a) Computational domain. SMP adapter in its (b) expanded and (c) compressed shapes.

Fig. 2. (a) Time-averaged velocity streamlines from the needle inlet and (b) instantaneous iso-Q surfaces without and with the SMP adapter.

Fig. 3. Time-averaged WSS (a) fields and (b) profiles along the bottom of the AV graft.

Fig. 4. (a) Needle delivery and (b) flow visualization within the AV graft model. (c) SMP adapter following delivery through the dialysis needle and thermal actuation. (d) Visualization of the SMP adapter flow.

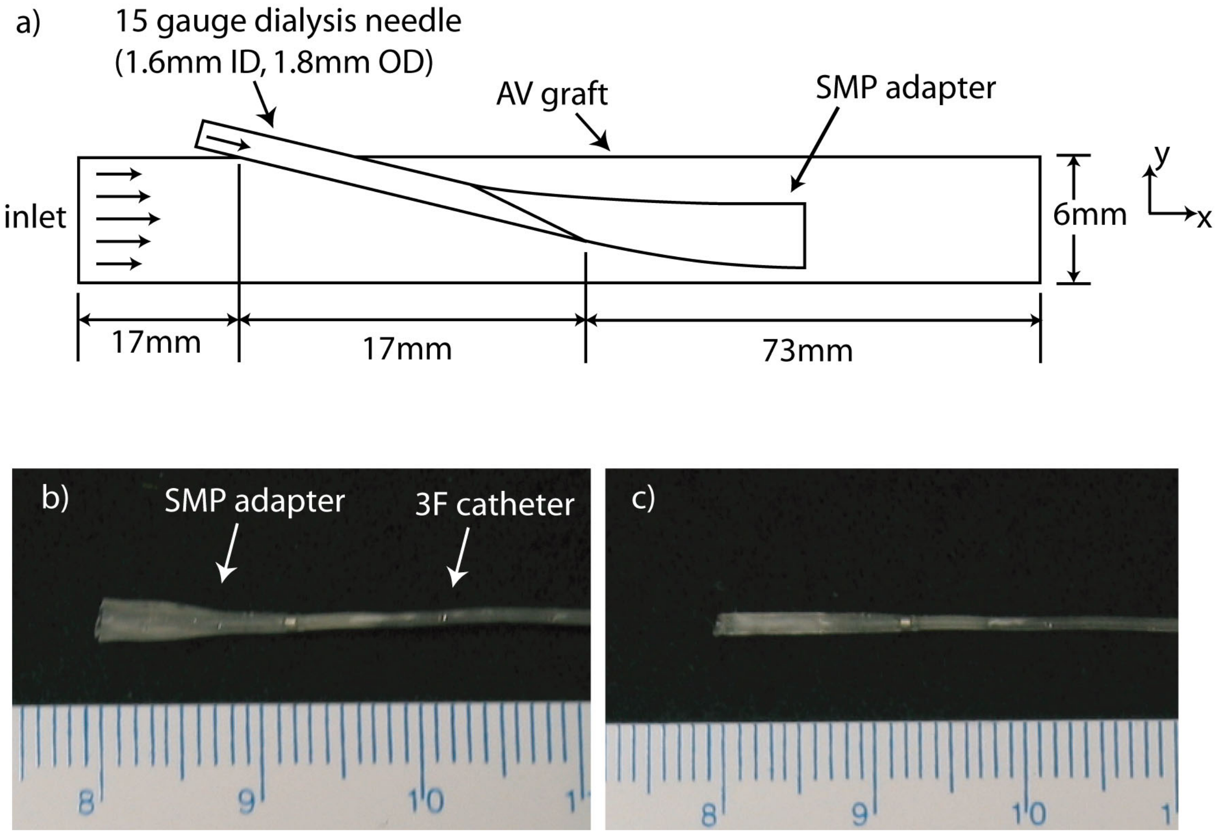
a)
15 gauge dialysis needle
(1.6mm ID, 1.8mm OD)
AV graft
SMP adapter
inlet
6mm
y
x
17mm
17mm
73mm
b)
SMP adapter
3F catheter
8
9
10
c)
8
9
10

Fig. **1**.

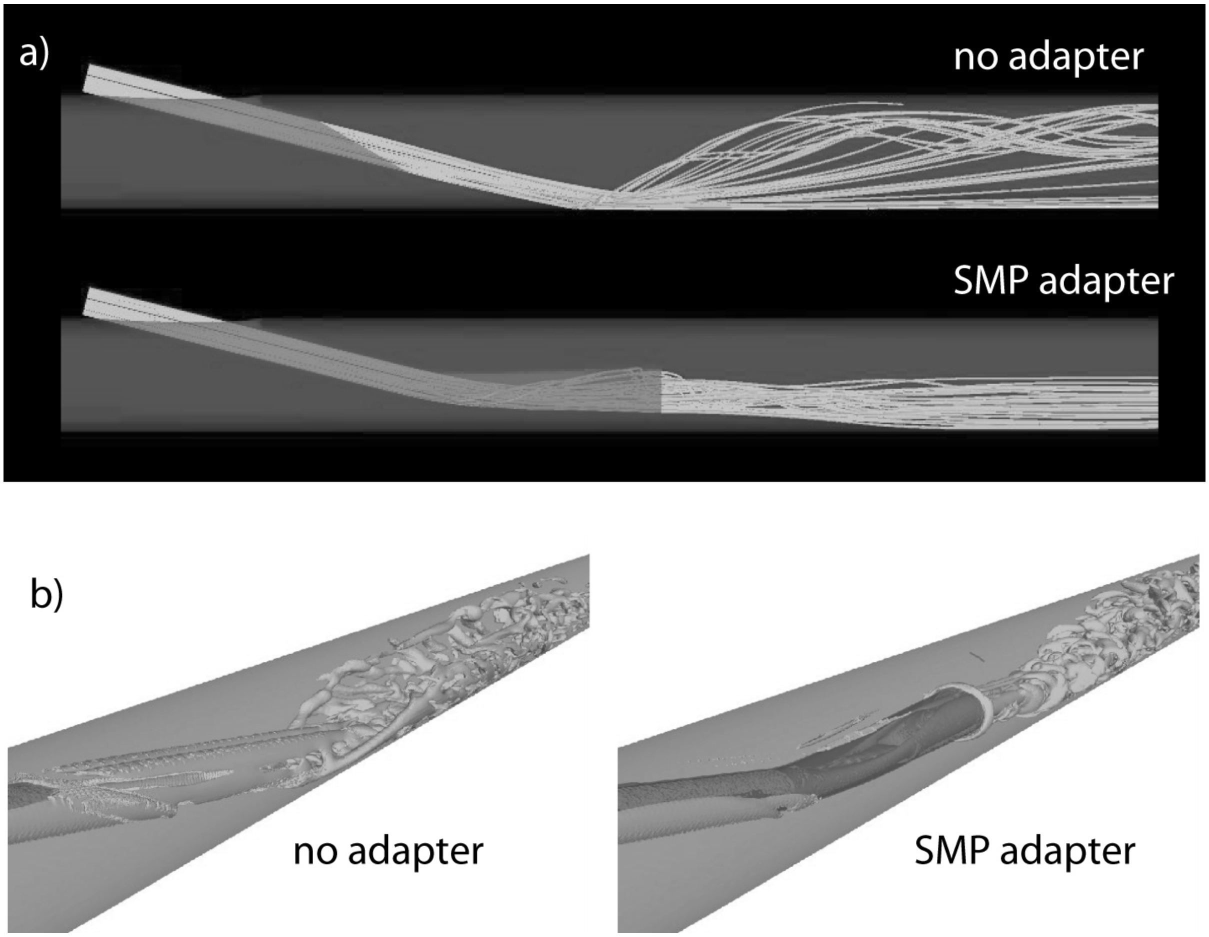

Fig. 2.

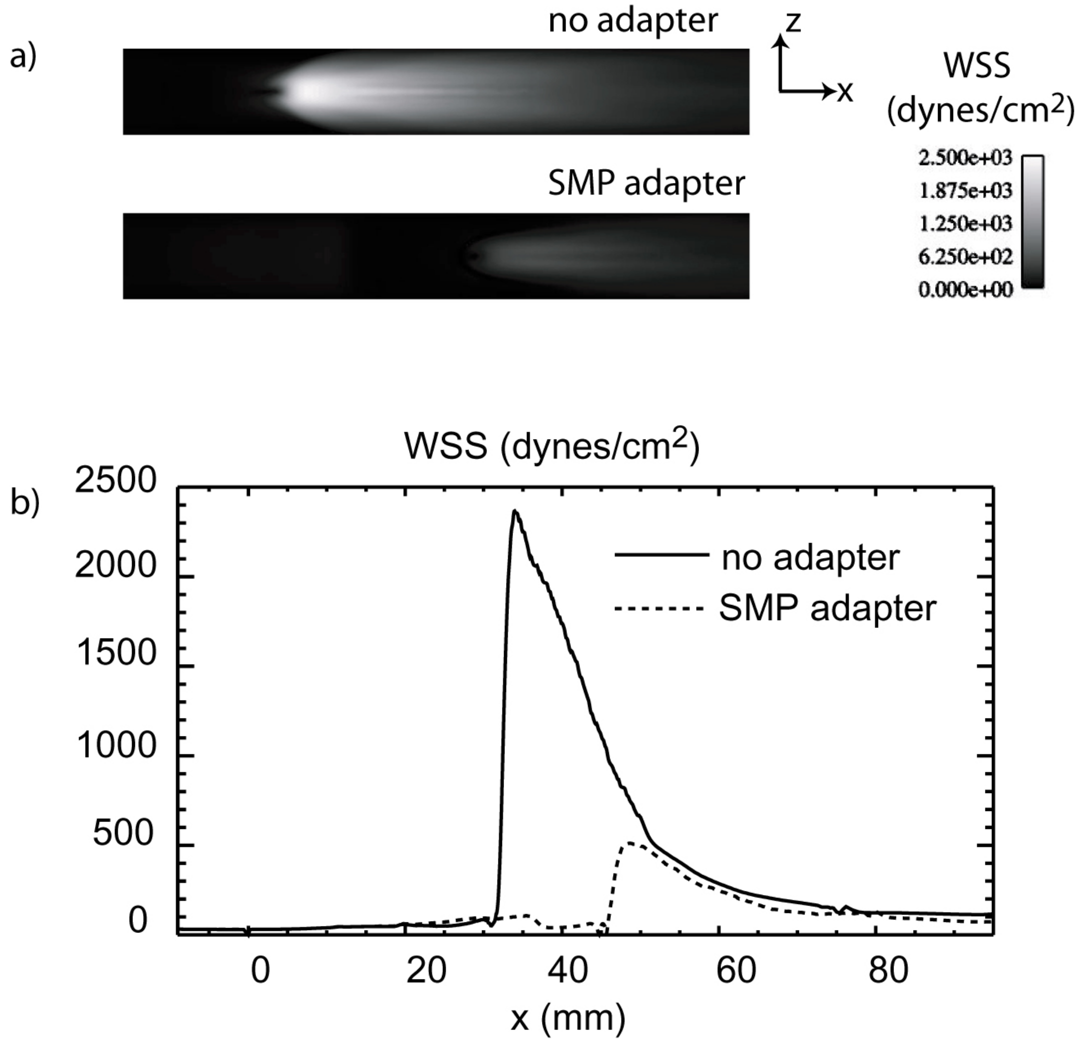
a)
no adapter
SMP adapter
z
x
WSS
(dynes/cm2)
2.500e+03
1.875e+03
1.250e+03
6.250e+02
0.000e+00
b)
WSS (dynes/cm2)
2500
2000
1500
1000
500
0
no adapter
SMP adapter
0
20
40
60
80
x (mm)

Fig. 3.

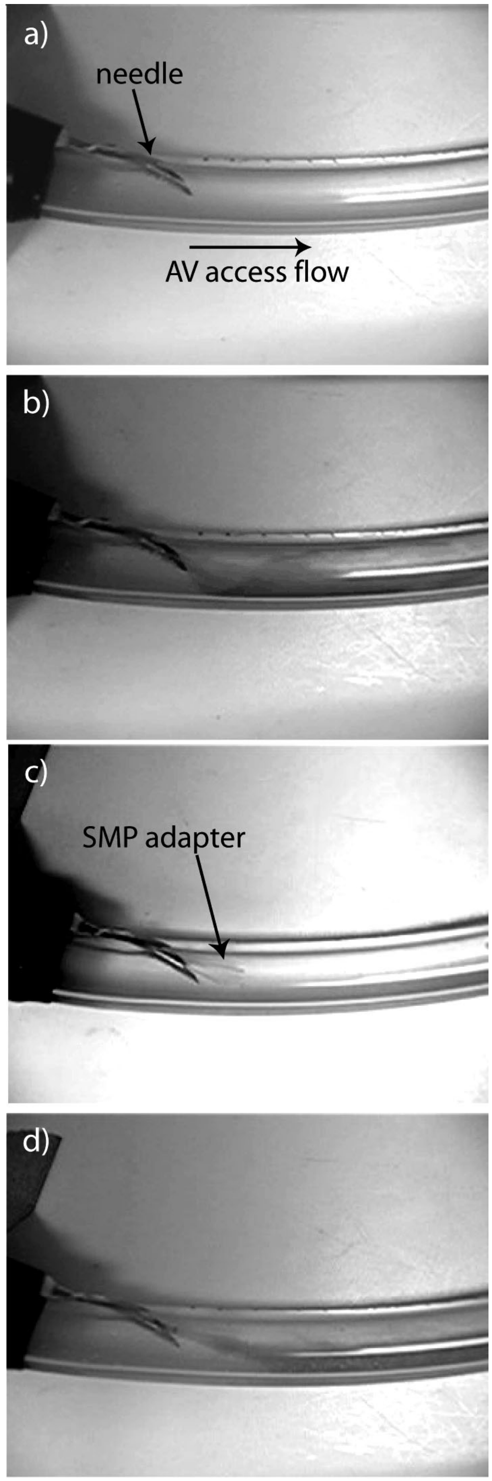

Fig. 4.